

DISCUSSION OF THE AMENDMENT

Claims 2-12 and 17-28 have been canceled. Claims 1 and 29 have each been amended by inserting the term --to a subject in need thereof--; by changing the word “means” with the synonymous --is--; by inserting punctuation, where applicable; and by deleting reference to an incorrect Chemical formula number. Claim 1 has been additionally amended by inserting the definition for “OPN”. Claim 29 has been additionally amended by inserting the word --treating--. Punctuation was inserted into other claims, where applicable.

No new matter is believed to have been added by the above amendment. Claims 1-4 and 29-34 are now pending in the application.

REMARKS

Applicants thank the Examiner and the Examiner's primary for the courtesy extended to Applicants' attorney during the interview held October 30, 2007, in the above-identified application. During the interview, Applicants' attorney explained the presently-claimed invention and why it is patentable over the applied prior art, and discussed other issues raised in the Office Action. The discussion is summarized and expanded upon below.

Due to the length of the specification herein, Applicants will cite to the paragraph number of the published patent application (PG Pub) of the present application, i.e., US 2007/0021418, when discussing the application description, rather than to page and line of the specification as filed.

Applicants continue to traverse the Election of Species Requirement, which requirement has **not** been made FINAL.

The presently-recited compounds are known, as described in the specification at paragraph [0026]. As described therein, the difference between the presently-claimed invention, and that disclosed in WO 99/25697 (Ohkuchi et al) is that Applicants have discovered that the compounds of Ohkuchi et al have an osteopontin (OPN) production inhibiting effect, and are thus effective in treating certain diseases in which OPN production is implicated, such as those recited in present Claim 33. Since only the utility for the presently-recited compounds need be searched, as Applicants' attorney pointed out during the above-referenced interview, there is no justification for an election of species with regard to the recited compounds, nor is there justification for an election of species with regard to a particular disease. There is clearly no undue burden in examining the presently-claimed invention, particularly as now claimed. Accordingly, it is respectfully requested that the Election of Species Requirement be withdrawn, and all the present claims be examined.

In addition, notwithstanding the Election of Species Requirement, there is no justification for holding Claims 2, 3, 30 and 31 withdrawn from consideration, since these claims also read on the elected species, as Applicants' attorney noted during the interview..

The rejection of Claims 1, 4, 29 and 32-33 under 35 U.S.C. § 102(b) as anticipated by US 6,348,468, which is equivalent to above-discussed WO 99/25697 (Ohkuchi et al), is respectfully traversed.

The present invention is drawn to methods, which is either a method of inhibiting osteopontin (OPN) production, comprising administering to a subject in need thereof an effective amount of a pyridazine derivative represented by formula (I) or a salt thereof, as recited in Claim 1, or a therapeutic method of treating a disease resulting from enhanced OPN production, comprising administering to a subject in need thereof an effective amount of a pyridazine derivative represented by formula (I) or a salt thereof, as recited in Claim 29. Thus, the present method claims are drawn to treating a specific universe of subjects. Ohkuchi et al, on the other hand, is drawn to treating a universe of subjects in which interleukin-1 β production is implicated. There is nothing in the prior art to suggest any nexus between interleukin-1 β production and OPN production, as advanced by Applicants' attorney during the interview.

The Examiner relies on the disclosure in Ohkuchi et al of ischemic nephritis (column 13, line 20), which the Examiner finds is a kidney disease, which kidney disease is a member of the Markush group in Claim 33 herein.

In reply, and as pointed out by Applicants' attorney during the interview, Claim 33 is limited by the requirement that the members of the disease Markush group require that it result from enhanced OPN production. There are, of course, many kidney diseases. Ischemic nephritis has not been shown to result from enhanced OPN production.

In addition, the Examiner finds that inhibiting OPN production is an inherent characteristic of the presently-recited pyridazine compounds.

In reply, of course it is inherent, but its inherency is Applicants' discovery herein. Indeed, every property of a compound is inherent. But Applicants are not **claiming** the compounds. Ohkuchi et al does not disclose or suggest methods of using their compounds to treat diseases implicated by OPN production.

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

The rejection of Claim 34 under 35 U.S.C. § 103(a) as unpatentable over Ohkuchi et al in view of McPhaden et al, *Plasma Osteopontin Levels in Multiple Myeloma*, Blood, J. American Society of Hematology, 1994; 84 (10, Suppl 1), page 172a, abstract 674 (McPhaden et al), is respectfully traversed. The deficiencies of Ohkuchi et al have been discussed above. McPhaden et al does not remedy these deficiencies. McPhaden et al simply discloses a connection between OPN production and multiple myeloma. However, Applicants do not profess to be the first to recognize this connection, as stated by Applicants' attorney during the interview. Rather, Applicants have discovered that certain compounds inhibit the production of OPN, and thus are useful for treating multiple myeloma. Neither McPhaden et al, nor any other prior art, discloses any connection or nexus between inhibiting interleukin-1 β production, as disclosed by Ohkuchi et al, and inhibiting OPN production. Accordingly, it is respectfully requested that this rejection be withdrawn.

The rejection of Claims 1, 4, 29 and 32-34 under 35 U.S.C. § 112, second paragraph, as indefinite, is respectfully traversed. The Examiner finds that it is not understood what is meant by "A means a single bond."

During the interview, the Examiner explained that the objectionable word in the above-quoted phrase is "means." As agreed, this word would be changed to --is-- in the

applicable claims. The Examiner acknowledged that he understood that “A is a single bond” simply means that R³ is connected to the applicable N directly.

The Examiner further finds that, alternatively, Claims 1 and 29 are indefinite because they do not provide antecedent basis for Claims 4 and 32 wherein R³ is unsubstituted phenyl.

In reply, Claims 1 and 29, respectively, each recite unsubstituted phenyl as a member of the R³ Markush group.

The Examiner further finds that Claims 1 and 29 fail to recite a host/subject patient to whom the effective amount of the pyridazine derivative will be administered. In reply, the claims have been so amended.

Finally, the Examiner finds that the term “OPN” fails to state the full meaning of the term at the first occurrence thereof.

In reply, Claim 1 has been so amended.

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

The provisional rejection of Claims 1, 4, 29 and 32-34 on the ground of nonstatutory obviousness-type double patenting over Claims 7-9 of copending Application No. 11/574,319 (copending application), is respectfully traversed. The Examiner finds that the term “prevention ... of rheumatoid arthritis in a subject” reasonably encompasses treatment of subjects with or without arthritis e.g. multiple myeloma.”

In reply, the Examiner has cited no evidence supporting any connection between prevention of rheumatoid arthritis and inhibiting of OPN production. Accordingly, it is respectfully requested that this provisional rejection be withdrawn.

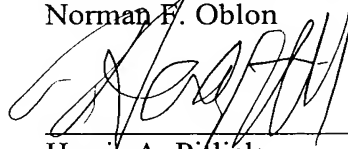
Application No. 10/566,253
Reply to Office Action of September 12, 2007

All of the presently-pending claims in this application are now believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'H. Pitlick', is written over a horizontal line.

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